



## U.S. Fish & Wildlife Service

### The Aquatic Animal Drug Approval Partnership Program

# Fact Sheet: 17- $\alpha$ Methyltestosterone INAD 11-236

[For detailed information see INAD Study Protocol]

<b>INAD objective/purpose:</b>	Collect supportive and pivotal data needed to establish the effectiveness of 17- $\alpha$ methyltestosterone when fed as a feed additive to larval tilapia to produce populations comprising over 90% male fish.
<b>Drug name:</b>	17- $\alpha$ methyltestosterone (MT)
<b>Source of drug/feed:</b>	Rangen Inc.
<b>Address:</b>	P.O. Box 706 Buhl, ID 83316
<b>Contact:</b>	Attention: David Brock Phone: 1-800-657-6446 x 3332 Fax: 208-543-8037 email: <a href="mailto:dbrock@rangen.com">dbrock@rangen.com</a>
<b>Target pathogen(s):</b>	Not Applicable
<b>Method of administration:</b>	Medicated-feed treatment
<b>Treatment dosage:</b>	9 milligrams (mg) MT per kilogram (kg) fish per day  <u>Note:</u> MT will typically be incorporated into standard tilapia feed at a rate of 60 mg MT per kg feed
<b>Treatment regimen:</b>	28 consecutive days
<b>Withdrawal period:</b>	Batch Culture: 120 days (from last day of treatment)  <u>Note:</u> Batch culture is defined as when all fish in a group/lot enter and leave the lot at the same time.  Partial Harvest/Restock Culture: individual minimum weight of 350 grams per fish  <u>Note:</u> Partial harvest/restock culture is defined as the mixing of different lots of fish during the grow-out period and selective harvest from the production unit at various times.
<b>Required test parameters:</b>	A minimum of once per calendar year, a minimum of 60 fish must be sampled from a specific treatment lot to determine the sex ration of the population. Investigator should also report general fish behavior and any adverse effects relating to treatment.
<b>Limitations or restrictions on use of drug:</b>	No re-treatment of fish is allowed. Investigator must follow all instructions in the Study Protocol for INAD 11-236 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.  Drug discharge must be in compliance with local NPDES permitting requirements.
<b>Required INAD fee:</b>	\$600.00 per facility per year
<b>AADAP Contact Information:</b>	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-587-9265 ext 136 Fax: 406-582-0242 email: <a href="mailto:bonnie_johnson@fws.gov">bonnie_johnson@fws.gov</a>
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